K092870

510(k) Summary

FEB 1 6 2010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: July 18, 2009

1. Company and Correspondent making the submission:

Name – Kunshan Deyi Plastic Co., Ltd.

Address – No. 270, Zhongjie Road. Shipu Street,

Qiandeng Town, Kunshan City

Jiangsu Province China

Telephone – +86-512-57408271

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Contact – Mr. Alan Zhou

Email – jacky_chen@deyiplastic.com

2. Device :

Trade/proprietary name: Disposable Vaginal Speculum

Common Name : Vaginal Speculum

Classification Name : speculum, vaginal, nonmetal

Predicate Device:

Predicate Model	Manufacturer	K Number	Submitted Device
Non-sterile DISPOSABLE VAGINAL SPECULUM	ZHEJIANG GONGDONG DEDICAL PLASTIC FACTORY	K050887	Non-sterile DISPOSABLE VAGINAL SPECULUM

3. Classifications Names & Citations :

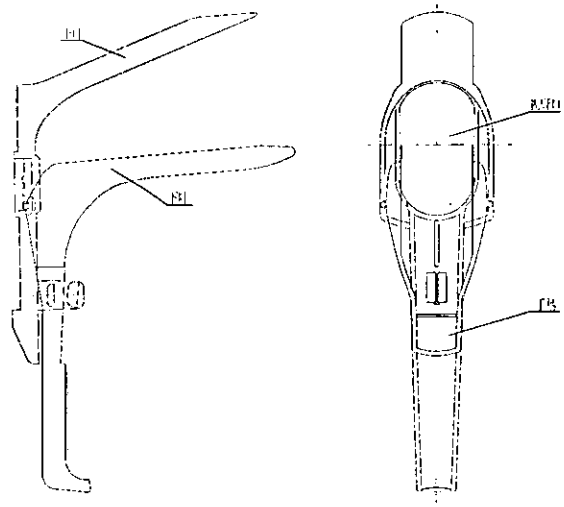
21CFR 884.4530, HIB, Speculum, Vaginal, Nonmetal

4. Product description :

The disposable vaginal speculum consists of up-foliage, under-foliage and handle with the specification of large, medium and small, which is used by medical department for examining female patients.

5. List of sizes and specifications :

Material	**Model**	**Bottom Diameter (d: mm)**	**Mouth Diameter (d: mm)**	**Height (H;MM)**
PS	Small	90	30	90
	Medium	100	38	110
	Large	118	45	115



6. Indication for use :

The disposable vaginal speculum is a non-sterile product and is to be used by a medical professional to visualize the interior of the vagina and cervix during obstetrical and gynecological examination.

7. Comparison with predicate device : (see table next page)

Comparison Table

Element of comparison	Subject Device	Claimed SE Device
Company	KUNSHAN DEYI PLASTIC CO., LTD.	ZHEJIANG GONGDONG DEDICAL PLASTIC FACTROY
FDA510(K) Number	N/A	K050887
Device Name	Non-sterile DISPOSABLE VAGINAL SPECULUM	Non-sterile DISPOSABLE VAGINAL SPECULUM
Intended use(s)	Same	The Non-sterile DISPOSABLE VAGINAL SPECULUM is non-sterile products and is intended to be used by a medical professional to expose the interior of the vagina to facilitate visualization during the obstetrical and gynecological procedures.
Production method	Same	injection molding
Material of construction	Same	Polyrex PG-33
View	Same	Providing clear plastic for viewing
Lateral wall protector	Same	Rests in the lateral wall protector to keep viewing clear; Rests in the lateral wall protector affording less chance of interfering with view of the vagina during procedures
Performance	Same	Hand operated, multi-position; Constructionally equivalent to the cooper speculum which has already been subjected to millions of applications;
Hand held and manually operated?	Yes	Yes
Heat to escape	Same	Has windows/Vent that allow heat to escape
Assembly	Same	Doesn't require assembly
Hand held and manually operated?	Yes	Yes
Design	Same	Dual, biparting blades
Single Use?	Yes	Yes
Sterile status	Non-sterile	Non-sterile
Mechanical safety	Same	Simple thumb adjustable lever action
Lubrication	Same	Non-Lubricated
Packaging	Same	Bulk pack 10/Plastic Bag, and Individually wrapped
Biocompatibility	Same	Complying with ISO10993
Anatomical sites	Same	Vaginal canal
Human Factors	Same	Single handed use, Self-locks in open position

Compatibility with the environment	Same	Disposable
Compatibility with the other devices	Same	Compatible with various spatula, Cyto brushes, packing forceps, sound and tenaculum, Tischler Bioposy forceps, scrapers, swabs and probes
Where used?	Same	By a physician; Professional medical facilities or office/clinical examination rooms

8. Safety and Performance Data :

Mechanical, environmental safety and performance testing have been accomplished according to standards YY0336-2002, Disposable Vaginal Speculum; ISO 10993-5 , Biological Evaluation for Medical Devices, tests for Cytotoxicicy; ISO 10993-10, Biological Evaluation for Medical Devices, tests for irritation and delayed type hyper sensitivity.

9. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Kunshan Deyi Plastic Co., Ltd. concludes that the disposable vaginal speculum is safe and effective and substantially equivalent to predicate devices as described herein.

10. Kunshan Deyi Plastic Co., Ltd. will update and include in a summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

FEB 1 6 2010

Kunshan Deyi Plastic Co., Ltd.
% Mr. Charles Mack, PE
Principal Engineer
International Regulatory Consultants
77325 Joyce Way
ECHO OR 97826

Re: K092870
Trade/Device Name: Disposable Vaginal Speculum
Regulation Number: 21 CFR §884.4530
Regulation Name: Vaginal Speculum, non-metal
Regulatory Class: II
Product Code: HIB
Dated: January 26, 2010
Received: February 1, 2010

Dear Mr. Mack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092870

Device Name: Disposable Vaginal Speculum

Indications for Use:

The disposable vaginal speculum is a non-sterile product and is intended to be used by a medical professional to visualize the interior of the vagina and cervix during obstetrical and gynecological examination.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K092870